

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference P 42 832 WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2004/003849	International filing date (<i>day/month/year</i>) 13 April 2004 (13.04.2004)	Priority date (<i>day/month/year</i>) 17 April 2003 (17.04.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant AESCULAP AG & CO. KG		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 11 sheets, including this cover sheet.																								
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 40%;">Box No. I</td> <td style="width: 50%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input checked="" type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 02 March 2006 (02.03.2006)
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PATENT COOPERATION TREATY

Translation

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year)

Applicant's or agent's file reference P 42 832 WO	FOR FURTHER ACTION See paragraph 2 below
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International application No. PCT/EP2004/003849	International filing date (day/month/year) 13.04.2004	Priority date (day/month/year) 17.04.2003
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International Patent Classification (IPC) or both national classification and IPC

Applicant AESCULAP AG & CO. KG
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1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II

Priority

1. ☒ The following document has not yet been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date in the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 27, 28

because:

☒ the said international application, or the said claims Nos. 27, 28

relate to the following subject matter which does not require an international preliminary examination (*specify*):

see Supplemental Box

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4, 10, 15-17, 26	YES
	Claims	1-3, 5-9, 11-15, 18-25	NO
Inventive step (IS)	Claims	15	YES
	Claims	4, 10, 16, 17, 26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO

2. Citations and explanations:

Reference is made to the following documents:

D1: EP-A-1216717

D2: GB1186796

D3: US-B-6264702

D4: EP-A-1216718

Lack of novelty

The present application does not meet the requirements of PCT Article 33(1), because the subject matter of claims **1-3, 5-14** and **16-25** is not novel within the meaning of PCT Article 33(2).

1. Document **D1** discloses (the reference signs between parentheses refer to this document) a planar implant comprising a planar support that is provided with two faces (figures 1-3), at least one face of the support being provided with an absorbable adhesive layer which is able to adhere to human and animal tissue (paragraph [0020], lines 3-8; according to the present application, claim 14, starch is a suitable adhesive; the wording of claim 1 also does not provide any information on how quickly the adhesive action is intended to be achieved;

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Box No. V

Reasoned statement under Rule 43bis 1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

D1 discloses explicitly (paragraph [0016], lines 38, 39) that tissue is intended to grow into the adhesive layer, that is to say adheres as well. Therefore, the subject matter of claim 1 is not novel.

2. It will be noted that, because of the extraordinary scope of claim 1, a great many documents disclose its subject matter. Reference is made in this connection to the search report. Even after clarification that the support comprises a self-adhesive layer, the subject matter would still be anticipated by document D2 (claim 1), with the result that the claim still does not meet the requirement for novelty.

3. The dependent claims 2, 3, 5-14 and 16-25 do not contain any features which, in combination with the features of any claim to which they refer, meet the PCT requirements for novelty (see document D1 and the corresponding passages cited in the search report).

Lack of inventive step

The present application does not meet the requirements of PCT Article 33(1), because the subject matter of claims 4, 10, 16, 17 and 26 does not involve an inventive step within the meaning of Article 33(3).

Claim 4: D3: figure 1

Claim 10: trivial design feature

Claims 16, 17: D2, page 6, line 1

Claim 26: paragraph [0072]

Positive appraisal

The combination of features that is contained in

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

dependent claim **15** is not known from the prior art, nor is it suggested by the prior art. The reasons for this are as follows: A distinguishing feature is represented by the use of dextran polyaldehyde as adhesive layer which contains at least 20% glucose units oxidized to the aldehyde. This feature solves the problem of achieving a strong adherence between implant and body tissue. No document in the available prior art discloses this feature. It would be at best suggested, from the prior art, to use dextran polyaldehyde as an example of a polysaccharide, but not with the claimed proportion of oxidized glucose units.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

4. The independent claim 1 has not been drafted in the two-part form defined by PCT Rule 6.3(b). However, in the present case the two-part form would appear to be appropriate. Accordingly, the features known in combination from the prior art (document D1) should have been placed in the preamble and the remaining features specified in the characterizing part.

5. Pursuant to PCT Rule 5.1(a)(ii), the description should have cited the nearest prior art documents from the search report and should have briefly outlined the relevant prior art contained therein. The applicant should make clear, in the description, which features of the subject matter of independent claim 1 are already known from the prior art.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The present application does not meet the requirements of PCT Article 6, because the claims use the expressions "more particularly" and "preferably", which lead to a lack of clarity. Since it is unclear whether the features behind these expressions belong or do not belong to the scope of protection, these features are considered entirely optional.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box III

The subject matter of claims **27** and **28** relates to a method for treatment of the human body by therapy, since the method step of producing an implant includes a therapeutic step aimed at restoring the health of the patient. Consequently, in accordance with Article 34.4(a)(i) and Rule 67.1(iv), no provisional opinion has been established in respect of these claims.